

Use of medicines outside of their UK Marketing Authorisation in pain management

This leaflet explains how some medicines are used differently to how they were originally developed and approved

How are medicines approved for use in the United Kingdom?

In the UK, medicines must have a licence, also called a Marketing Authorisation (MA), before they are approved for treating patients.

The licence is confirmation that the medicine has been tested for safety and is of an appropriate quality. It also outlines what conditions the medicine is approved for use in, what the doses should be and any precautions for its use.

What do the terms 'off-Label' and 'off-Licence' mean?

The licence does not prevent a doctor from prescribing the medicine for other uses as long as the doctor is satisfied that it is effective and safe in those circumstances. This is known as 'off-label' or 'off-licence' use.

Why are medicines used 'off-label' or 'off-licence'?

Sometimes evidence shows that a medicine can also be used in circumstances outside of its original licence; and there may be clinical situations, when the 'off-label' use of medicines, may be judged to provide you with the most suitable treatment.

For example, the antidepressant nortriptyline is effective at treating certain types of pain, but it does not have a licence for this use.

What differences might I notice if I am prescribed or supplied with an off-label medicine?

In certain settings, because off-label or unlicensed medicines are so often used, it may not be highlighted to you. However, at other times, your doctor or pharmacist will point out that you are being given an off-label or unlicensed medicine, explain why it is the preferred treatment and discuss its safety and effectiveness with you.

If you are given any further written information, please read it carefully.

You may notice that a manufacturer's information leaflet supplied with the medicine is not specific to you. For example, you may notice that it does not include information about the condition for which you are being treated, or it may state a dose that is different from that which the doctor has prescribed.

A common example of this is the use of certain antidepressant and epilepsy medicines to treat pain. These have a licence for the treatment of depression or epilepsy but not pain and so the information leaflet enclosed with the medicine does not refer to pain.

What should I do if I have any concerns about the medicine I have been given?

Whether within licence or not, whoever prescribes you the medicine should also provide you with a clear explanation of how to take it, the expected benefits and possible side effects.

If you experience a side effect from any medicine, you should first tell your doctor or another member of the health-care team.

You are also encouraged to report any side effects using the Yellow Card Scheme – go to www.mhra.gov.uk to find out more.

What do I do if I want more information?

Please talk to your doctor or pharmacist. They are knowledgeable and experienced with medicines and will be pleased to answer your questions.

For More Information Contact:

Name:

Telephone:

Job Role:

Version 1.2

Midlands and Lancashire CSU

Approved: October 2022

Review date: October 2025